UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,858	08/20/2001	Friedrich Altmann		5615

7590 12/06/2006

Burns, Doane, Swecker & Mathis
PO Box 1404
Alexandria, VA 22313-1404

EXAMINER	
MCGARRY, SEAN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,858	ALTMANN, FRIEDRICH	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-52,57,58,60-63,76,77,83,84 and 108-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-52,57,58,60-63,76,77,83,84 and 108-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/08/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Official Action is in response to applicants papers filed 10/10/06. Those rejections made in the previous Official Action and not addressed below are withdrawn. Claims 49-52, 57, 58, 60-63, 76, 77, 83, 84, and 108-135 are pending and under examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-52, 57, 58, 60-63, 76, 77, 83, 84, and 108-135 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. This rejection is maintained for the same reasons of record set forth in the official action mailed 4/03/06.

The specification discloses SEQ ID NO: 1, which corresponds to the cDNA encoding the mung bean species of α1, 3-fucosyl transferase. SEQ ID NO: 1 and antisense and ribozymes targeted thereto meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to encompass methods

that use, cells that contain and vectors that contain sequences that are, and ribozymes that bind to and sequences that encode ribozymes that bind to; sequences that hybridize to SEQ ID NO: 1 under specified conditions, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. The claims also embrace methods of making cells that contain the broad scope of sequence where the practitioner is required to first find the sequence. The claims embrace sequences from plants, insects and host cells in general. The range of species from which the sequence(s) is/are derived is unlimited. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. The specification discloses only one example of a plant sequence (Mung bean) and provides no basis for what the structure of other plant α1, 3-fucosyl transferase sequences would be. It is stated, for example, at page 3, that the specificity of the enzyme from human cells is quite different than that of plant cells, for example. One in the art must rely on the broad range of potential and undescribed sequences to construct antisense/ribozyme expression vectors, cells containing such, vectors expressing ribozymes that may cleave undescribed mRNA. The claims embrace sequences that have 50% identity with SEQ ID NO: 1 and those that hybridize under conditions recited in the claims and have a specified activity. No such sequences have been described other than SEQ ID NO: 1.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997);

In *re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical

characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only those embodiments drawn to SEQ ID NO: 1, but not the full breadth of the claims (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The invention is drawn to vectors that contain a DNA which is inversely orientated with respect to a promoter where the sequence is 50% homologous to SEQ ID NO: 1 or which hybridizes to SEQ ID NO: 1 under specified conditions. The vector produces an antisense transcript of the DNA which antisense is intended to inhibit a GlcNAc-α1, 3-fucosyl transferase in cells that contain such a vector, a DNA molecule encoding a ribozyme targeting a plant α1, 3-fucosyl transferase nucleic acid as defined in claim claims 51 and 52) which inhibit a plant α1, 3-fucosyl transferase in cells (claims 62, 63, 76, 77, 83,and 84). The construction of the antisense and ribozyme expression vectors for use in the claimed invention require a description of the specific plant α1, 3-

fucosyl transferase sequences targeted. For example, at 50%, a ribozyme is not even required to target any sequence corresponding to SEQ ID NO: 1, but perhaps the other 50% that is not identical. One in the art would need to have in their possession the sequences that are homologous to SEQ ID NO: 1 or which hybridize to SEQ ID NO: 1 in order to make the nucleic acids that encode the recited ribozymes or antisense. The instant specification provides only a potential method of isolating nucleic acids from which they would then make the nucleic acids claimed or used in the claimed methods, for example. As has been set forth above, only one such sequence, SEQ ID NO: 1, has been described in the instant specification. The instant specification does not provide any specific ribozyme sequences or antisense sequences other than those that are completely complimentary to a target nucleic acid sequence based on SEQ ID NO: 1, for example. The specification fails to provide any specific structure such that one in the art would know what structures would be required for the specific inhibition of any of a wide scope of plant α1, 3-fucosyl transferase nucleic acid targets embraced within the instant claims. No specific structure function relationship has been established in the specification or in the prior art for the antisense and ribozyme sequences for use in the instant invention, The specification also fails to provide an adequate description in figures or words since there is no disclosure of the structures of the target nucleic acids let alone the structures of the antisense and ribozyme sequences instantly claimed, for example. The specification provides only trial and error methods that may find embodiments embraced within the scope of the claimed invention.

Applicants arguments filed 10/03/06 have been fully considered but they are not persuasive.

Applicant argues that the hybridization conditions recited in the claims. Applicant argues that the structure of the claimed nucleic acids are related to and defined by their function. At the outset it is clear that applicant has not appreciated the entirety of the examiners rejection and arguments. Applicant appears to base their arguments only on the structure of the sequence encoding the fucosyl transferase when the invention is drawn to sequences at least 20 nucleotides in length that correspond to antisense/ribozyme embodiments. For example applicant does not address at all the issue set forth in the Official Action at page 7. Applicant arguments do not take into context the rejection as a whole. Applicant has still not yet provided, for example, an explaination of how one in the at would now the structure of a 20mer antisense or a ribozyme that is targeted or is represented by a sequence that is part of a sequence that hybridizes or that is 50% homologous to SEQ ID NO:1 where the antisense or ribozyme is part of the 50% that is not homologous or that does not provide for hybridization. That said, applicant arguments set forth in their reply will be addressed.

Applicant argues that the office has indicated that the recited hybridization conditions are not identical to the conditionsprovided in the Written Description Guidelines. Applicant asserts that the office did not adduce any sound scientific reason that the recited conditions do not qualfy as high stringency for the claimed sequences and assert that the office only states that the conditions are not identical to the example provided in the guidelines. It should be pointed out the , as stated in the examiners

arguments, the example provided in the guidelines also provided evidence of other sequences that were produced under the hybridization conditions and that those other sequences evidenced little variation. The instant specification does not provide such a correlation and applicants reponse provides no evidence or argument that would show by correlation that would be the case in the instant application. Applicant provides Exhibit "A" as evidence that applicant actually used the conditions recited in the claims to identify fucosyl transferase enzymes. This Exhibit provides little in so far as evidence since it only shows the conditions and does not provide the sequences that were islolted and further the information therein is not attested. The information provided in Exhibit B only shows that hybridization conditions can be varied. It is unclear how Exhibit B provides evidence of the stringency of the conditions recited in the claims would correspond to those in the Guidelines.

Applicant again argues that the sequences encoded [i.e. the antisense and ribozymes] need not actually encode a protein having fucosyl transferase activity but would only need to hybridize with the target sequence. And again the examiner responds that since the utility of the invention would be to inhibit the expression of a nucleic acid encoding protein having fucosyl transferase activity one would indeed have to know what the target sequence is [not only the target at large but the specific region targeted (e.g. a 20mer region included in the claimed vector)].

In regard to applicants argument for claims 57, 58 and 61, 63 and 108-119 where applicant asserts that all the steps have been described, the examiner would point out that one in the at would not recognize that applicant was in possession of vectors that

comprise, for example 20 mer sequences that are targeted to a sequence that is the non-homologous part of a sequence that has 50%[70%, 80%. . .etc.) homology to SEQ ID NO: 1. it is noted that claims 108-11 are drawn to recombinant host cells which are required to have a described nucleic acid sequence transfected therein.

Applicant's arguments filed 1/12/06 were considered but they were not persuasive. The examiners arguments set forth in the Official Action mailed 4/03/06 are repeated below for clarity of the record since applicant has repeated arguments provided in their previous response.

Applicant argues that the inclusion of the specified hybridization conditions overcomes the grounds of rejection. Applicant points to the Revised Interim Written Description Guidelines Training Materials at Example 9 for support of their arguments. Applicant asserts that as in the example one in the art would not expect substantial variation among the species encompassed within the scope of the claims containing the hybridization limitation. It is noted that in coming to their conclusion applicant has neglected to realize the differences in the facts of the instant application and that of the example. For example the example uses "highly stringent" conditions that include 6XSSC and 65 degrees Celsius. The instant invention recites .5M NaPO4 and 42 degrees Celsius. The Example provides that the specification showed that several of the nucleic acid molecules that hybridized had the same activity as the exemplified SEQ ID NO: 1. The instant specification does not provide such a disclosure. Applicant asserts that the conditions recited would provide for such but provides no evidence or

arguments that would show that would be true. It is the position of the examiner that the condition instantly recited are not equivalent to the "highly stringent" conditions of the Example 9.

Applicant argues that the sequences encoded [i.e. the antisense and ribozymes] need not actually encode a protein having fucosyl transferase activity but would only need to hybridize with the target sequence. Since the utility of the invention would be to inhibit the expression of a nucleic acid encoding protein having fucosyl transferase activity one would indeed have to know what the target sequence is.

Applicant argues that claims 57, 58 and 61 are directed to method of preparing hosts containing vectors and argue that these claims are different since, for example claims 49-52 are directed to molecules containing certain structural features and the instant claims are directed to method steps. It is noted that all of claims 57, 58 and 60 require one in the art to obtain a sequence with specified function where it is not clear that the specification has shown that one in the art would immediately recognize that any of a genus of nucleic acid sequences within the scope of structures allowed [50% or the specified hybridization conditions] would have the function required. The question is has applicant described the invention such that one in the art would know by looking at a sequence that, for example is 57% homologous to SEQ ID NO: 1 would have the function of SEQ ID NO: 1 without screening for its activity? It is the Examiners position that the specification has not described the invention such that one would know a core structural motif or a sufficient number of species such that one would know that any particular compound would have the function required by the claims. It is noted that

applicant asserts that there are mosses that have fucosyl transferase identities of 50-60% and are functionally the same at the enzyme level. It is unclear the context of this argument. Are applicants comparing moss to moss for 50-60% or are applicants comparing moss to SEQ ID NO: 1 and if so is it along the entire sequence or a part? It is unclear what applicant relies on with this argument.

Claims 57, 58, 61, 63, 108-119, and 124-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is drawn to either nucleic acids that are 50% homologous to SEQ ID NO: 1 or the use thereof. The instant specification provides one sequence SEQ ID NO: 1, which has a specified function. The claimed invention is drawn to any nucleic acid that is 50% homologous and has the same activity as SEQ ID NO: 1. The specification has therefore provided merely a starting point and in an invitation to further experimentation. One in the art would be required to perform and undue amount of trial and error experimentation in order to practice the invention as claimed. One in the art must use only SEQ ID NO: 1 to establish what other sequences within the broad scope now claimed would have the function required by the claims. The instant specification fails to provide more that a starting point for more experimentation in order to practice the invention. Although the amount of experimentation is not dispositive in the

evaluation of the enablement of an invention, it is the position of the examiner that the sheer volume of experimentation, whether it is routine experimentation or not, required for the instant invention in view of the lack of guidance in the specification, the unpredictability of the art in general and the instant invention in particular renders the instant invention not to be enabled. It is noted that the scope of the invention is open to any organism and the breadth of the claims is therefore vast.

Applicant's arguments filed 10/03/2006 have been fully considered but they are not persuasive.

Applicant argues that the specification provides a method to find sequences. Applicant also provides Exhibit "D", a declaration of a Dr. Iain Wilson. Dr Wilson is not an inventor, does not refer to this application, and the information provided therein is not attested in this application and will not be considered.

Exhibit "E" is purported to show that the results shown therein were achieved using the claimed methods. This assertion is not apparent from the Exhibit and such an assertion has not been attested for the evidence provided as Exhibit "E".

Applicant has not addressed the rejection as is pertains to the scope of that claimed and the undue amount of trial and error experimentation required to practice the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635